

# EXHIBIT 11

VIA EFS

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:	:		
Declan Walsh <i>et al.</i>	:		
	:		
Conf. No.: 6857	:	Group Art Unit:	2876
	:		
Appln. No.: 14/699,567	:	Examiner:	Daniel A. Hess
	:		
Filing Date: April 29, 2015	:	Attorney Docket No.:	026723-5043-US-06
	:		
Title:	:		
DOSE COUNTER FOR INHALER AND METHOD FOR COUNTING DOSES	:		

**AMENDMENT UNDER 37 C.F.R. § 1.116**

The following Amendment is submitted in response to the Office Action dated October 20, 2016 (Paper no. 20161017) and the Advisory Action dated March 13, 2017. The Amendment is being timely filed in view of the simultaneous submission of a three-month Petition for Extension of Time up to and including April 20, 2017 including payment of fees, under 37 C.F.R. § 1.136(a), filed herewith.

Also enclosed herewith is a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114. The Office is requested to not enter the prior unentered amendment filed on February 21, 2017.

Except for issue fees payable under 37 C.F.R. § 1.18, the Director is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. **50-0310** (Billing No. 026723-5043-US-06). This paragraph is intended to be a Constructive Petition For Extension Of

Please amend the above-identified application as follows:

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**AMENDMENT TO AND LISTING OF THE CLAIMS**

Please amend the claims as follows. This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Currently Amended) A dose counter for a metered dose inhaler having a body arranged to retain a medicament canister of predetermined configuration for movement of the medicament canister relative thereto, the medicament canister containing an active drug; the dose counter comprising:

a ratchet wheel having a plurality of circumferentially spaced teeth,

an actuator comprising an actuator pawl arranged to engage with a first tooth of the ratchet wheel, wherein the actuator can be driven in response to canister motion to drive the ratchet wheel to rotate,

a count pawl arranged to engage with a second tooth of the ratchet wheel, wherein as the ratchet wheel is driven by the actuator to rotate, the count pawl rides along a forward surface of the second tooth and resiliently jumps over the second tooth,

a dosage indicator associated with the count pawl,

wherein the actuator is arranged to define a first reset position in which the actuator pawl is brought into engagement with the first tooth; and

wherein the actuator is further arranged such that, during a canister fire sequence, when the actuator is in a second position, which is after the first reset position and at a canister fire configuration, the medicament canister fires medicament before the dose counter reaches a count configuration, and when the actuator is in a third position after the second position, the count pawl resiliently jumps over the second tooth and the dose counter reaches the count configuration, whereby the dosage indicator has indicated a count.

~~wherein the canister fire sequence comprises a canister fire configuration and a count configuration wherein:~~

~~— in the canister fire configuration the actuator pawl and ratchet wheel are in a first position at which the canister fires medicament, and~~

~~— in the count configuration the actuator pawl is in the first position or in a second position which is just after the first position, and in the count configuration the count pawl has just resiliently jumped over the second tooth and the dosage indicator has indicated a count.~~

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2. (Previously Presented) A dose counter as claimed in Claim 1 in which the actuator is displaced less than 1 mm relative to the body between its locations in the canister fire and count configurations.

3. (Cancelled)

4. (Previously Presented) A dose counter as claimed in Claim 1 wherein the dosage indicator includes a tape with incremental dose indicia located thereon, the tape being positioned on a tape stock bobbin and arranged to unwind therefrom.

5. (Currently Amended) A dose counter as claimed in Claim 1 in which the actuator and ratchet wheel are arranged to provide a start configuration at which the actuator is spaced from the ratchet wheel, ~~a reset configuration at which the actuator is brought into engagement with the ratchet wheel during the canister fire sequence~~, and an end configuration at which the actuator disengages from the ratchet wheel during the canister fire sequence.

6. (Previously Presented) A dose counter as claimed in claim 5 in which:

(a) the actuator is arranged to be located about 1.5 to 2.0 mm from its location in the fire configuration when in the start configuration;

(b) the actuator is arranged to be located about 1.0 to 1.2 mm from its location in the fire configuration when in the reset configuration; or

(c) the actuator is arranged to be located about 1.1 to 1.3 mm from its location in the fire configuration when in the end configuration.

7. (Previously Presented) A dose counter as claimed in Claim 5 in which the body includes a formation for forcing the actuator to disengage from the ratchet wheel when the actuator is moved past the end configuration.

8. (Previously Presented) A dose counter as claimed in claim 1, wherein the count pawl and the ratchet wheel are arranged to permit one way incremental relative motion therebetween.

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9. (Currently Amended) A dose counter as claimed in Claim 8 in which the actuator and ratchet wheel are arranged to provide a start configuration at which the actuator is spaced from the ratchet wheel, ~~a reset configuration at which the actuator is brought into engagement with the ratchet wheel during the canister fire sequence,~~ and an end configuration at which the actuator disengages from the ratchet wheel during the canister fire sequence and in which the count pawl is substantially fixedly mounted on the body and in which the count pawl is arranged to be capable of repeatedly engaging the teeth of the ratchet wheel in anti-back drive interlock configurations as the dose counter is operated, the count pawl being positioned so that the ratchet wheel is halfway, or substantially halfway, moved from one anti-back interlock configuration to the next when the actuator and ratchet wheel are in the end configuration thereof.

10. (Previously Presented) An inhaler comprising the body arranged to retain the medicament canister of predetermined configuration and the dose counter as claimed in claim 1.

11. (Previously Presented) An inhaler as claimed in Claim 10 in which the body includes a canister-receiving portion and a separate counter chamber; the body, ratchet wheel and actuator being located inside the counter chamber, the body of the inhaler having wall surfaces separating the canister-receiving portion and the counter chamber, the wall surfaces being provided with a communication aperture, an actuation member extending through the communication aperture to transmit canister motion to the actuator.

12. (Previously Presented) The dose counter as claimed in Claim 4, wherein the incremental dose indicia on the tape is in the form of even numbers and the body includes a dose marker that points to a location either at one of the even numbers or between two adjacent even numbers.

13. (Previously Presented) A dose counter as claimed in claim 5 in which:

(a) the actuator is arranged to be located about 1.5 to 2.0 mm from its location in the fire configuration when in the start configuration;

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(b) the actuator is arranged to be located about 1.0 to 1.2 mm from its location in the fire configuration when in the reset configuration; and

(c) the actuator is arranged to be located about 1.1 to 1.3 mm from its location in the fire configuration when in the end configuration.

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**REMARKS**

1. Claims 1-2 and 4-13 are currently pending in the application, as amended. Claims 1, 5, and 9 have been amended. Support for the amendment can be found throughout the originally filed application, at least in original claim 5, paragraphs [0153]-[0154] and Figs. 10C-10D. Thus, no new matter has been added.

All amendments presented herein are made solely to expedite prosecution of the application without admission as to the propriety of the rejections set forth in the present Office Action and without acquiescence to the Examiner's characterization of the claims or cited reference. Applicant respectfully reserves the right to include claims of the same or different scope as previously written in one or more continuing applications.

This Amendment is being simultaneously filed with a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114.

***Claim Rejections – 35 U.S.C. § 102***

2. The Examiner rejected claims 1, 3-4, and 10-11 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,446,627 to Bowman *et al.* (hereinafter "Bowman"). Claim 3 is cancelled rendering this rejection moot.

Claim 1 has been amended without admission as to the propriety of the rejection and without acquiescence to the Examiner's characterization of the claims or cited reference. Amended claim 1 of the present application recites:

A dose counter for a metered dose inhaler having a body arranged to retain a medicament canister of predetermined configuration for movement of the medicament canister relative thereto, the medicament canister containing an active drug; the dose counter comprising:

a ratchet wheel having a plurality of circumferentially spaced teeth,

an actuator comprising an actuator pawl arranged to engage with a first tooth of the ratchet wheel, wherein the actuator can be driven in response to canister motion to drive the ratchet wheel to rotate,

a count pawl arranged to engage with a second tooth of the ratchet wheel, wherein as the ratchet wheel is driven by the

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actuator to rotate, the count pawl rides along a forward surface of the second tooth and resiliently jumps over the second tooth, a dosage indicator associated with the count pawl, wherein the actuator is arranged to define a first reset position in which the actuator pawl is brought into engagement with the first tooth; and wherein the actuator is further arranged such that, during a canister fire sequence, when the actuator is in a second position, which is after the first reset position and at a canister fire configuration, the medicament canister fires medicament before the dose counter reaches a count configuration, and when the actuator is in a third position after the second position, the count pawl resiliently jumps over the second tooth and the dose counter reaches the count configuration, whereby the dosage indicator has indicated a count.

(emphasis added)

Bowman does not disclose each and every element of amended claim 1 and in particular does not disclose the above underlined limitation in the combination as claimed. For example, Bowman does not disclose a first reset position in which the actuator pawl is brought into engagement with the first tooth and ...during the canister fire sequence, when the actuator is in a second position, which is after the first position and at a canister fire configuration, the medicament canister fires medicament before the dose counter reaches a count configuration, and when the actuator is in a third position after the second position, the count pawl resiliently jumps over the second tooth and the dose counter reaches the count configuration, whereby the dosage indicator has indicated a count, as claimed.

In rejecting claim 1, the Examiner points to Fig. 3 of Bowman and notes that “it is reasonable to expect that the engagement bar 351 starts in a position disengaged from the teeth of the ratchet wheel 360, and then will engaging [sic] with the teeth during firing, and will finally disengage from the teeth as it moves upward again after firing.” Following that logic, however, Fig. 3 necessarily illustrates a point in a firing sequence in which the canister fires before engagement bar 351 engages with the teeth of ratchet-toothed wheel 360. Bowman does not expressly describe the position of the engagement bar 351 in relation to the ratchet-toothed wheel 360 of Fig. 3 or the position of the drive pawl 451 with respect to the ratchet-toothed wheel 460 of Fig. 4 when the dose is delivered. Bowman merely states that “the counter must only index after the metering valve has delivered its dose from the inhaler” *Id.* at col. 4, lines 39-42.

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Bowman is silent as to the firing sequence position of a device including the features illustrated in Fig. 4. In connection with the embodiment of Fig. 3, Bowman describes “a friction clutch 364 which serves to restrain the axle 363 against reverse rotation and hence prevents reverse travel of the counter tape 368.” *Id.* at col. 8, lines 50-54. Bowman refers to the prevention of any reverse rotation of the axle as a “stepless” restraint. *Id.* at col. 9, lines 58-61. Bowman differentiates the “stepless” restraint from a “stepped” restraint of a ratchet and fixed pawl system which “permits a degree of reverse rotation...” *Id.* at col. 9, lines 16-20. Thus, indexing using the stepless restraint in Fig. 3 of Bowman occurs throughout the engagement of the hook element and the ratchet-toothed wheel where any degree of rotation of the ratchet-toothed wheel, and thus the counter, is locked in by the friction clutch. If the hook element were to rotate the ratchet-toothed wheel prior to delivering the dose, indexing could occur without the dose actually being delivered. As the Examiner notes, Bowman states that “the counter must only index after the metering valve has delivered its dose from the inhaler.” Final Office Action, p. 5 (quoting Bowman at col. 4, lines 39-42). It follows, therefore, that hook element 351 does not engage the ratchet-toothed wheel 360 until after the dose is delivered. Thus, Fig. 3 of Bowman does not teach or suggest “a first reset position in which the actuator pawl is brought into engagement with the first tooth; and...when the actuator is in a second position, which is after the first reset position and at a canister fire configuration, the medicament canister fires medicament before the dose counter reaches a count configuration,” as recited in claim 1.

Regarding the embodiments in Figs. 4 and 6a of Bowman, Bowman is silent as to when the drive pawl 451 engages the ratchet tooth 461 during a firing sequence. Applicant respectfully submits that one would expect an ordinary artisan to apply the firing sequence taught by Bowman regarding the embodiment of Fig. 3 to all the embodiments disclosed by Bowman, including the embodiments of Figs. 4 and 6a. Thus, Bowman teaches away from the claimed invention because it teaches to not move (index) the counter before firing. Bowman neither anticipates nor renders obvious claim 1 as written because Bowman teaches that the hook element may not engage the ratchet wheel until after the dose is delivered.

The Applicant therefore respectfully asserts that claim 1 is allowable as written and respectfully requests reconsideration of the rejection of claim 1. Claims 4 and 10-11 depend from claim 1 and are therefore allowable for at least the same reasons that claim 1 is allowable.

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***Claim Rejections – 35 U.S.C. § 103***

3. The Examiner rejected claims 2, 5-9, and 12-13 under 35 U.S.C. § 103(a) as unpatentable over Bowman. Claims 2, 5-9, and 12-13 depend upon claim 1 and are patentable over Bowman for at least the same reason discussed above. Accordingly, Applicant respectfully requests that the rejection of claims 2, 5-9, and 12-13 be reconsidered and withdrawn.

**CONCLUSION**

4. Each and every ground of each rejection in the outstanding office action has been addressed herein. To the extent a particular argument in support of a rejection by the Examiner is not expressly addressed, that argument is moot in view of the foregoing and Applicant does not acquiesce to any such argument or the Examiner's characterization of the cited references.

In view of the foregoing Amendment and remarks, Applicant respectfully submits that the present application, including claims 1-2 and 4-13, as amended, is in condition for allowance and such action is respectfully requested. Should the Examiner determine otherwise, Applicant's representatives suggest a telephone interview in order to expedite prosecution of the application.

Respectfully submitted,

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